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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,237	12/01/2003	Adrian Forster	FORSTER1	9763

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EXAMINER	
STULII, VERA	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,237	FORSTER ET AL.	
	Examiner	Art Unit	
	Vera Stulii	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, and 5-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the xanthohumol-containing hop extract" in line 2. There is insufficient antecedent basis for this limitation in the claim, because the claim does not set forth that a xanthohumol-containing hop extract was produced.

Claim 3: It is not clear what applicant means by "usual, supercritical CO_2". What "usual" stands for? It is also not clear how hop pellets where "pre-extracted with usual, supercritical CO_2"? Is there a specific temperature/pressure range for this step? What "pre-extracted" stands for? It is also not clear what applicant means by "dissolved ingredients". It is not clear how "dissolved ingredients are **separated together with** the xanthohumol-concentrated hop extract". What is being separated from what? How exactly the separation is being done?

Claims 5: has a same problem as claim 3. The meaning of "separation" is not clear.

Claims 6: has a same problem as claim 3. The meaning of "separation" is not clear.

Claim 7: It is not clear what "pre-extract" means. How is it different from "the xanthohumol-concentrated extract"? It is also not clear how "the xanthohumol-concentrated extract is separated from the pre-extract"? It is also not clear what is meant by "first step" and "second step". What is the meaning of "extract, usual for brewing"? Claim 7 has the same problem as claim 3 related to separation step.

In claim 8: It is not clear what applicant means by "stable powder that need no drying and is free from additives". Is it already dry powder?

Claims 9-13 provide for the use of xanthohumol-concentrated hop extract, where xanthohumol-concentrated hop extract is used as an admixture to solid, pastry or liquid food, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. The claims are indefinite where they merely recite a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-13 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuhrts (US 2003/0228369).

In regard to claim 1, 2 Kuhrts et al. discloses supercritical carbon dioxide extraction [0043]. Kuhrts et al. teaches that "CO_2 is the most commonly used material in supercritical fluid extraction and fractionation. Supercritical CO_2 extraction also allows for better separation and fractionation of certain components in hops" [0043]. Kuhrts et al. also teaches that extraction of hops yields high concentration of alpha acids [0047] and one of the primary alpha-acids is xanthohumol. [0045]. As evidenced by wikipedia.org, by "definition a supercritical fluid is a substance above both its critical temperature and pressure", where "for carbon dioxide the critical point is located at 304.1K (30.95°C) and 7.38Mpa (73.8 bar)" (p.2, § 1). Therefore, supercritical carbon dioxide is carbon dioxide at temperature above 30.95°C and pressure above 73.8 bar, which is in the range recited by applicant.

In regard to claim 8, Kuhrts et al. discloses producing powders from high viscosity fluids by mixing high viscosity fluid and absorbing agent (Abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (US 2003/0228369) in view of Erdelmeier et al. (US 2005/0042318) and Babish et al. (US 2003/0113393).

In regard to claims 3-7 Kuhrts et al. discloses use of hop pellets [0044] in supercritical CO_2 extraction.

Kuhrts et al. are silent about subsequent extractions with CO_2 under supercritical conditions. However, Erdelmeier et al. teach one or more extractions of a hop drug using supercritical CO_2 [0023], "preferably carried out once, twice or three times, particularly three times" [0028].

Kuhrts et al. are also silent about separation of xanthohumol-concentrated hop extract. However, Babish et al. teach a step of solvent removal after extraction [0014]. Babish et al. teach "the removal of CO_2, however, simply involves a release of pressure to volatilize the CO_2" [0014].

As evidenced by Erdelmeier et al., it is well known in the art to carry out several extractions of hop material using supercritical carbon dioxide in order to increase content of prenylated chalcones (xanthohumol). It would have been obvious to one skilled in the art to subject hop pellets to several subsequent extractions using supercritical carbon dioxide as a solvent in order to produce a extract with a high content of xanthohumol as taught by Erdelmeier et al. As evidenced by Babish et al. it is well known in the art to remove supercritical carbon dioxide from the extract in order to achieve a higher concentration of extract by simply release the pressure to volatize the carbon dioxide. Thus, it would also have been obvious to one skilled in the art to separate the CO_2 as a solvent after extraction by releasing the pressure to volatize the CO_2 as taught by Babish et al.

Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (US 2003/0228369) in view of Ohnogi et al. (US 2004/0002423).

Kuhrts (US 2003/0228369) discloses a process of producing powders from high viscosity fluids such as xanthohumol concentrated extracts.

Kuhrts (US 2003/0228369) is silent about admixing powders into solid, pasty or liquid food, appropriate organic solvent such as ethanol, concentration of ethanol, and method of adding extract to food.

Ohnogi et al. (US 2004/0002423) disclose "food, beverage or feed for enhancing growth factor production, comprising an extract from *Humulus lupulus* (hops)" [0035]. Ohnogi et al. (US 2004/0002423) teaches "an ethanol extract derived from *Humulus lupulus* ... may be contained in food or beverage" [0157].

Conveying process is well known in the art as a method of continuous addition. As evidenced by Ohnogi et al., it is well known in the art to add ethanol based hop extracts to food and beverages. It would have been obvious to one skilled in the art to add xanthohumol-concentrated hop extract in either dry form as taught by Kuhrts or in ethanol based form as taught by Ohnogi et al. in order to produce a product that enhances growth factor. It would also have been obvious to one skilled in the art to employ conveying process for continuous addition in order to optimize the process. It would have been obvious to one skilled in the art to determine the particular percentage of xanthohumol-concentrated hop extract in the solution by routine experimentation in order to achieve the optimal result.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Stulii whose telephone number is (571) 272-3221. The examiner can normally be reached on 7:00 am-3:30 pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VS

V. Shukla 07/24/06

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